SOPP 8401.7: Action Package for Posting

Version # 3

Effective Date: December 5, 2011

I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff for the development and assembly of Action Packages for Posting, pursuant to Section 916 of the Food and Drug Administration Amendments Act (FDAAA) of 2007.

II. Scope

This procedure applies to original Biologics License Applications (BLAs) and New Drug Applications (NDAs) processed within CBER.

III. Background

Per FDAAA, Action Packages for original BLAs or NDAs are required to be posted to the Food and Drug Administration's (FDA) Web site within 30 calendar days of approval for new products or within 30 calendar days of the third Freedom of Information Act (FOIA) request for the action package. A summary review (Summary Basis of Regulatory Action [SBRA]) is required to be posted within 48 hours of approval unless redaction is required.

The FDAAA language specifies that the following types of documents be included in the posted Action Package:

- Documents generated by the FDA related to review of the application.
- Documents pertaining to the format and content of the application generated during drug development.
- Labeling submitted by the applicant.
- A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any non-concurrence with review conclusions.
- Decision documents of product office Division Directors and Office Directors, including:
  - a brief statement of concurrence with the summary review;
  - a separate review or addendum to the review if disagreeing with the summary review; and
  - a separate review or addendum to the review to add further analysis.
- Identification by name of each officer or employee of the FDA who:
  - participated in the decision to approve the application; and
  - consented to have his or her name included in the package.

There are certain Web-posting policies that must be considered when developing and assembling Action Packages for posting. These policies are set using legal mandates and technical requirements that must be followed to successfully comply with FDAAA, Americans for Disabilities Act (ADA) for accessibility under Section 508 of the Rehabilitation Act of 1972 (Section 508), and other federal statutory requirements. Web-posting policies are found under the Policy section of this SOPP.

IV. Definitions

A. **Action Package for Posting** – consists of those documents that get posted to the Biologics section of the FDA Web site after an approval. Examples of the documents include:

- Summary Basis of Regulatory Action (SBRA)
- Discipline review memos
- Meeting minutes held with applicants
- Telecons with substantive discussions. (Refer to *SOPP 8104: Documentation of Telephone Contacts with Regulated Industry*.)

B. **Administrative Record** - Administrative record means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action. (21 CFR 10.3). Administrative records include sponsor/applicant submissions, CBER/FDA generated documents, and CBER/FDA database records.

C. **Administrative File** –Administrative file means the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations (21 CFR 10.3).

D. **Document Security Password** – For purposes of this SOPP, the document security password refers to the password placed on an Adobe Acrobat Portable Document Format (PDF) document prior to circulation to prevent changes to the PDF document. This password must be removed prior to certification of the document and importation into CBER's Electronic Document Room (EDR). Please refer to regulatory job aid *JA 810.01: Document Security Passwords* for instructions on how to set or disable document security passwords.

E. **Regulatory Management System/Biologics License Applications (RMS-BLA)** - database that manages the Center's biologics licensing processes.

F. **Substantive Communications** – communications that add new information or change old information in a submission. These communications include discussions involving clarification or resolution of an issue or one that was the basis of a decision. FDA requests for information are always considered substantive.

V. Policy

Web Posting Policies

A. The Agency is required by law to post documents that are compliant with Section 508. The Agency is also required to meet Department of Health and Human Services (DHHS) standards. (see references)

B. All CBER generated documents should be provided in Microsoft (MS) Word, MS Excel or, for emails, in Rich Text Format (RTF) or Text (TXT) formats. Documents shall not be recreated for this purpose. If a given document exists ***only*** in Portable Document Format (PDF), and the MS Word file cannot be found, supply the document as a PDF document. Please note that all PDF documents must have the document security password removed.

C. Due to Section 508 compliance concerns, all images, including scanned tables/documents and logos should have text included that describes the content. If these document types are included as part of a review memo, the text describing the image, logo, table or scanned document should be included. Please refer to regulatory job aid *JA 815.02 How to Add Alternative Text to Images in Microsoft Word* for additional information.

D. Submission of documents to CBER Websites including action packages for posting shall follow document formatting requirements found in *SOPP 8105: Submitting Documents for the CBER Web Sites.*

Action Package for Posting Policies

E. Prior to posting the Action Package on FDA's Website, all documents in the Action Package must be reviewed for disclosure per applicable regulations and statutes. Any information exempt from disclosure, such as confidential commercial, trade secret, etc., will be redacted.

F. CBER product offices must ensure that all appropriate documents are included in the Action Package for Posting. All Action Packages for Posting, including the approval letter and package insert (PI), are sent to the Office of Communication, Outreach, and Development (OCOD) immediately upon approval of original BLAs or NDAs so the statutory time frames for posting Action Packages can be met.

G. Telecons or emails that contain significant discussion of the product that contributed to a decision are part of the Action Package for Posting. All other telecons or emails are part of the Administrative File. Refer to *SOPP 8104: Documentation of Telephone Contacts with Regulated Industry* and *SOPP 8119: Use of Email for Regulatory Communications* for additional information.

H. **Only the last email in an email string shall be included in the Action Package for Posting. The last email should include all emails in the string; therefore, do not include each individual email in the string as a separate communication**. Refer to *SOPP 8119: Use of Email for Regulatory Communications* for additional information.

I. **Document security passwords set on PDF documents during circulation to prevent changes must be removed prior to certification of the document and importation into CBER's EDR.** If the document security password is still in place, OCOD will not be able to access the PDF document for continued processing.

J. Information or data submitted to CBER in only PDF format and used as part of a CBER generated document that will be included in the Action Package for Posting should be identified and **must** adhere to Web-posting requirements. An example of this information type is the inclusion of a table from the applicant's submission that is included in the discipline review memo.

1. If the PDF information or data is included in the CBER generated document, the transmittal memo should clearly indicate that this is the only available form of the document. Refer to regulatory template *T 910.01: Transmittal Memo Template*.

2. The PDF must meet all the requirements for Section 508, including the accompanying text for images, logos, tables, and scanned documents.

K. The Officer/Employee list will contain the names of employees who wrote, co-wrote, and/or signed off on reviews or decisional memos, participated as part of the review team and who consent to being identified on the list. Refer to regulatory template *T 910.02: Officer/Employee List Email Template*.

1. For a review carried out by a team, the name of each team member who consents will be included on the list regardless of who signed the review.

2. Before or at the time of approval of the application, employees (as defined above) will be asked whether they consent to have their names included on the list. Due to the statutory deadlines for posting Action Packages, employees are asked to respond to this inquiry within seven (7) business days.

3. Only the names of employees who respond in writing that they consent will be included on the list.

4. There will be no change in redaction of employee names from FDA records. Employee names will be redacted from FDA records only when it is consistent with the Freedom of Information Act and 21 CFR 20.32. The names of FDA employees may be included in disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

5. In most cases, the name of an employee who has written, co-written and/or signed-off on reviews or decisional memos will still be associated with the documents he/she has authored and will be publicly

disclosed, even if the employee's name is excluded from the Officer/Employee List.

VI. Responsibilities

A. Review Team

Responsible for Section 508 compliance for all CBER generated documents related to the submission review and importing them into CBER's EDR prior to approval.

Responsible for ensuring all documents for posting imported into CBER's EDR include the certified PDF version with the MS Word version attached.

B. Product Office Regulatory Project Manager (RPM)

Responsible for developing and assembling Action Packages for posting immediately upon approval of an original BLA or NDA.

C. Review Committee Chair

For NDAs: Responsible for working with the RPM to ensure the documents retrieved from CBER's EDR and placed on the CBER Share Drive by OCOD/EDT are the documents identified by the RPM and are the correct documents for posting.

For BLAs: Responsible for working with the RPM to ensure the documents identified in RMS-BLA as "Post to Web" are the correct documents for posting.

D. Division Director (DD) or Office Director (OD) with product responsibility

Oversees the development and assembling of the Action Package for Posting [DD]; signs the Transmittal Memo to OCOD [OD].

E. OCOD/Division of Disclosure and Oversight Management (DDOM)/Electronic Disclosure Team (EDT)

Responsible for retrieving the Action Package documents from CBER's EDR as identified by the product offices, review for disclosure and redaction of those documents, and communication with the OCOD/ Division of Communication and Consumer Affairs (DCCA)/Communication Technology Branch (CTB) when the documents are ready for posting.

F. OCOD/Division of Communication and Consumer Affairs (DCCA)/Communication Technology Branch (CTB)

Responsible for posting Action Package documents on FDA's Internet Website once redacted and communicating with product office RPMs to inform them that the posting has been completed.

VII. Procedures

A. Send an email to *CBER-OCOD-Action Packages* to get an OCOD Point of Contact (POC) approximately four (4) weeks prior to approval. The product office will inform OCOD of their POC at the same time. **[RPM]**

B. Ensure all appropriate documents are finalized and imported into CBER's EDR following Web-formatting requirements prior to routing the package for approval (signature from Office Director). **[review team members]**

C. Ensure all documents for posting and imported into CBER's EDR include the certified PDF version with the MS Word version attached. **[review team members]**

D. Ensure that documents for inclusion in the Action Package for Posting are consistent with Web-formatting requirements. **[RPM, review team members]** Please refer to the following regulatory job aids on CBER's Intranet Web page for additional information:

1. JA 810.01: Document Security Passwords

2. JA 815.02: How to Add Alternative Text to Images

3. JA 815.03: How to Group Images

4. JA 815.04: How to Set Table Properties

E. Ensure document security passwords have been removed from all PDF documents prior to certification and importation into CBER's EDR. **[RPM, review team members]**

F. Ensure Transmittal memo is signed by the Office Director responsible for the file. **[RPM; DD/OD]**

1. For NDAs: the Transmittal memo will indicate all appropriate documents for posting are identified on the attached EDR list.

2. For BLAs: the Transmittal memo will indicate all appropriate documents for posting are marked as "Post to Web" in RMS-BLA and located in the Action Package for Posting folder in CBER's EDR.

G. Provide OCOD the transmittal memo, approval letter, the package insert and the Summary Basis of Approval (SBRA) in MS Word format in an email to *CBER-OCOD-Action Packages* **on the date of approval** in order to facilitate the 48 hour posting requirement. **[RPM]** The subject line for this email should contain the STN and "new approval."

H. For original BLAs:

1. Confirm the "Post to Web" checkbox in RMS-BLA is completed accurately for all documents to be posted. This will automatically place the documents in the Action Package folder in the EDR. Refer to

regulatory checklist *C 910.01: Action Package for Posting Checklist* for additional information. **[RPM]**

2. Retrieve all of the documents from the Action Package folder in the EDR **[OCOD/DDOM/EDT]**

I. For original NDAs:

1. Attach to the transmittal memo a list of documents to be posted (Action Package for Posting) and where to locate the documents within CBER's EDR using the Action Package for Posting checklist. Refer to regulatory checklist *C 910.01: Action Package for Posting Checklist* for additional information. **[RPM]**

2. Retrieve the NDA documents identified by the product office RPM from CBER's EDR and place on the identified CBER Share Drive. **[OCOD/DDOM/EDT]**

3. Notify the product office RPM and Committee Chair via email that the NDA documents are available on the CBER Share Drive for review prior to redaction and posting. **[OCOD/DDOM/EDT]**

4. Confirm, **within one business day of notification**, the NDA documents placed on the CBER Share Drive are accurate and should be posted. **[RPM; Committee Chair]**

5. Remove the documents from the CBER Share Drive once confirmation is received from the product office. Documents will be placed on an internal OCOD Share Drive until processing is completed. **[OCOD/DDOM/EDT]**

J. If a document for posting needs to be replaced due to formatting changes, delete the old document from CBER's EDR using current EDR deletion policies and procedures. **[RPM]**

K. Once the document is replaced in CBER's EDR, send a copy of the document with an explanation about which document is being replaced via email to *CBER-OCOD-Action Packages* for redaction. **[RPM]** The subject line for this email should contain the STN and "replacement document."

L. Review for disclosure and redact the Action Package documents according to Center and Agency policies and procedures. **[OCOD/DDOM/EDT]**

M. Notify the Communication Technology Branch when the documents have been placed on the Internal OCOD Share Drive and are redacted and ready for posting. **[OCOD/DDOM/EDT]**

N. Post the Action Package on FDA's Internet Website according to Center and Agency policies and procedures. **[OCOD/DCCA/CTB]**

O. Notify the RPM by email once the posting is completed. **[OCOD/DCCA/CTB]**

P. Delete the documents on the Internal OCOD Share Drive once the posting is completed and confirmed. **[OCOD/DCCA/CTB]**

Q. If a document already posted as part of the action package for posting needs to be replaced in CBER's EDR: **[RPM]**

1. Send a copy of the document with an explanation about which document is being replaced, the reason for the replacement, and whether or not there needs to be a replacement on CBER's Web page via email to *CBER-OCOD-Action Packages* for redaction.

2. The subject line for this email should contain the STN and "replacement document."

3. Documents that need to be replaced on CBER's Web page are those that contain text changes to the document.

VIII. Appendices

N/A

IX. References

A. References below are located on CBER's Intranet Web Page (unless otherwise noted)

1. Regulatory Job Aids

   a. JA 810.01: Document Security Passwords

   b. JA 815.02: How to Add Alternative Text to Images in MS Word

   c. JA 815.03: How to Group Images in MS Word

   d. JA 815.04: How to Set Table Properties in MS Word

2. Regulatory Checklist

   a. C 910.01: Action Package for Posting Checklist

3. Regulatory Templates

   a. T 910.01: Transmittal Memo Template

   b. T 910.02: Officer/Employee List Email Template

4. SOPP 8105: Submitting Documents for the CBER Websites

B. Web links to the references below can be found in the list following the History Table.

1. SOPP 8104: Documentation of Telephone Contacts with Regulated Industry
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079463.htm

2. SOPP 8119: Use of Email for Regulatory Communications
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm109645.htm

3. Freedom of Information Act (FOIA)
http://www.justice.gov/oip/foia_guide09/foia-final.pdf

4. 21 CFR § 20.32.
http://edocket.access.gpo.gov/cfr_2004/aprqtr/21cfr20.32.htm

5. Section 916, "Action Package for Approval" of FDAAA
http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110

6. People with Disabilities, Section 508 of the Rehabilitation Act of 1973
http://www.access-board.gov/sec508/guide/act.htm

7. Section508.gov http://www.section508.gov

8. Department of Health and Human Services (DHHS) Section 508 General Information http://www.hhs.gov/web/508/index.html

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Dixon, Burk	Robert A. Yetter, PhD	November 22, 2011	3	Revised to include information consistent with new EDR functionality
Dixon, Burk	Robert A. Yetter, PhD	October 19, 2010	2	Revised to include additional use of RMS-BLA
BPS/RMCC	Robert A. Yetter, PhD	May 6, 2010	1	First issuance of this SOPP.